DETAILED ACTION

This action is in response to the applicant's amendment received 25 January 2012. The application is not in condition for allowance for the reasons set forth below. Claims 2, 4, 6, 8, 10, and 12 remain cancelled. Claims 5 and 7 remain withdrawn from consideration.

Response to Arguments

Applicant's arguments filed 25 January 2012 with respect to claims 1, 3, 9, and 11 have been fully considered but they are not persuasive.

The applicant first argues that the recited "attachment" requires a physical connection and Kensey fails to disclose a "physical connection" between the elongate body 32 and occlusion member 30. However, the applicant has not described such a special definition in the disclosure. Furthermore, figure 8 fails to show any "physical connection" between the occluding member (220) and the elongate body (235). Figure 8 simply discloses the two being attached by attaching the member to an assembly (227), the assembly being simply disposed within the elongate member. Therefore, it is the examiner's position that the elements can be considered an attachment as claimed and rejection is maintained.

The applicant then argues that Kensey fails to disclose an occlusion member configured to be withdrawn from the lumen of the blood vessel, substantially blocking the flow out of the blood vessel. However, Figure 2 clearly shows the member can fit through the opening and into the vessel, and thus it is capable of being withdrawn from the lumen of the blood vessel and deployed outside the vessel to block blood flow out of

the vessel. Therefore, it is the examiner's position that Kensey discloses the function as now required by amended claims 1 and 9.

The applicant finally argues that the combination of Kensey and Belhe is improper, since element 38 of Kensey would obstruct the bleed back lumen of Belhe. However, Belhe discloses the use of tubular members through the elongate member such that they do not obstruct the bleed back lumen (for example, see Figures 2A, 2E, and 3). Furthermore, Kensey's tubular element 38 is designed to move freely within the elongate member. Therefore, it is the examiner's position that Kensey's elongate member can accommodate element 38 while providing bleed back functionality, and thus the rejection is maintained.

Claim Objections

Claims 1 and 9 are objected to because of the following informalities: unclear language. Claims 1 and 9 require the lumen extend between the openings and contact the occlusion member, yet also require the occlusion member be distal from the first opening on distal region. Therefore, the language is unclear. Furthermore, claims 1 and 9 require the occlusion member be attached "on" the distal region of the elongate member, yet also require the lumen contact the occlusion member. The term "on" should be replaced by --within--. Since it is understood from the applicant's disclosure that the lumen extends from the proximal end to the distal end of the elongate member and that the occlusion member is attached to a specific position within the elongate member (according to the embodiment shown in Figure 8 that requires the member and

lumen be in contact), only an objection is being made. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (U.S. Patent No. 4,744,364) and Belhe et al. (U.S. Pub. No. 2004/0215232 A1).

Kensey discloses a locator device (see entire document) comprising an elongate member (32), wherein the distal region has a substantially uniform diameter (for example, see Figure 1), and a bioabsorbable and expandable occlusion member (30; for example, see column 3, lines 53-54 and 66) releasably attached by an attachment (the relationship between 36 and 38 serve as the attachment) to a specific position on the elongate member (on the distal position; for example, see Figure 1), wherein the

device and its components are capable of performing the functions claimed. Kensey further discloses the elongate member comprises a lumen in contact with the occlusion member (for example, see Figure 1), but fails to disclose a distal opening and a proximal opening connected by the lumen, wherein the occlusion member is located distally of the distal opening such that blood can enter the distal opening, flow through the lumen, and exit the proximal opening without passing through the occlusion member.

Belhe also discloses a locator device comprising an elongate member (12) for locating a blood vessel and delivering an occlusion member (for example, see Figure 2D). Belhe teaches providing the elongate member with distal (18) and proximal (20) openings connected by the lumen of the elongate member such that blood may pass therebetween to provide the operator with visual feedback as to the position of the elongate member (blood flow indicates the elongate member is within the vessel or artery and lack of blood flow indicates the elongate member is outside of the blood vessel or artery; for example, see paragraph 35). Therefore, to provide Kensey's elongate member with proximal and distal openings as taught Belhe would have been obvious to one having ordinary skill in the art at the time the invention was made. Doing so would provide visual feedback to the operator as to the location of the device, thus ensuring proper positioning of the occlusion member. Kensey's occlusion member is located on the distal end of the distal portion of the elongate member and Belhe teaches providing the distal opening proximal of the distal end on the distal portion of the elongate member. These teachings yield the occlusion member located distally of the

distal opening. Furthermore, to provide the occlusion member distal of the distal opening would have been obvious to one having ordinary skill in the art at the time the invention was made to ensure the occlusion member does not interfere with the distal opening prior to and/or during deployment of the occlusion member.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-90629062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Corrine McDermott, at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Primary Examiner, Art Unit 3773
February 27, 2012